

## •Original research article•

# A community-based controlled trial of a comprehensive psychological intervention for community residents with diabetes or hypertension

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**Background:** Depression and anxiety often occur in persons with chronic physical illnesses and typically magnify the impairment caused by these physical conditions, but little attention has been paid to this issue in low- and middle-income countries.

**Aim:** Evaluate the effectiveness of a community-based psychological intervention administered by non-specialized clinicians and volunteers for alleviating depressive and anxiety symptoms in individuals with chronic physical illnesses.

**Methods:** A total of 10,164 community residents receiving treatment for diabetes or hypertension in Shanghai were arbitrarily assigned to a treatment-as-usual condition (n=2042) or an intervention condition (n=8122) that included community-wide psychological health promotion, peer support groups, and individual counseling sessions. The self-report Patient Health Questionnaire (PHQ-9), Generalized Anxiety Disorder scale (GAD-7), and 12-item Short-Form Health Survey (SF-12) assessed depressive symptoms, anxiety symptoms, and quality of life at baseline and after the 6-month intervention.

**Results:** Among the 8813 individuals who completed the baseline assessment, 16% had mild or more severe depressive or anxiety symptoms (PHQ-9 or GAD-7  $\geq 5$ ) and 4% had moderate or severe depressive or anxiety symptoms (PHQ-9 or GAD-7  $\geq 10$ ). The education component of the intervention was effectively implemented, but only 31% of those eligible for peer-support groups and only 9% of those eligible for individual counseling accepted these interventions. The dropout rate was high (51%), and there were significant differences between those who did and did not complete the follow-up assessment. After adjusting for these confounding factors, the results in individuals who completed both assessments indicated that the intervention was associated with significant improvements in depressive symptoms ( $F=9.98$ ,  $p<0.001$ ), anxiety symptoms ( $F=12.85$ ,  $p<0.001$ ), and in the Mental Component Summary score of the SF-12 ( $F=16.13$ ,  $p<0.001$ ). There was, however, no significant change in the self-reported rates of uncontrolled diabetes or hypertension.

**Conclusions:** These results support the feasibility of implementing community-based interventions to reduce the severity of depressive and anxiety symptoms in persons with chronic medical conditions in low- and middle-income countries where psychiatric manpower is very limited. However, there are substantial methodological challenges to mounting such interventions that need to be resolved in future studies before the widespread up-scaling of this approach will be justified.

**Keywords:** depression; anxiety; community intervention; diabetes; hypertension; community medical service; China

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## 1. Introduction

Diabetes and hypertension are two common chronic illnesses that are quite prevalent in China: 26.7% of the adult population (265 million individuals) has primary hypertension<sup>[1]</sup> and 11.6% (110 million individuals) has adult-onset diabetes.<sup>[2]</sup> Studies in other countries report that individuals with diabetes and hypertension are more likely to have depressive disorders and anxiety disorders than individuals without these physical illnesses.<sup>[3,4]</sup> Moreover, compared to persons with hypertension or diabetes who do not have comorbid depression or anxiety, those with comorbid depression or anxiety are less likely to adhere to medication regimens, have a lower quality of life, experience an earlier onset of complications, and have higher mortality rates and higher medical costs.<sup>[5,6]</sup>

Several studies report the effectiveness of psychological interventions for depression and anxiety in individuals with diabetes or hypertension.<sup>[7,8]</sup> However, most of these studies suffer from significant limitations: they (a) are targeted to the relatively small number of individuals who meet diagnostic criteria of major depressive disorder or anxiety disorder, excluding the much larger number of individuals with mild to moderate depressive and anxiety symptoms; (b) involve a single type of individual-based treatment (medication, cognitive behavioral therapy, etc.) that requires a high level of expertise to administer; (c) focus on the reduction of depressive or anxiety symptoms with little consideration of other important outcomes such as quality of life, changes in the severity of the physical disorder, overall treatment costs, and family burden; and (d) have sample sizes that are too small and too unrepresentative to assess the effect of the intervention on all community members with hypertension or diabetes.

In China little attention has been paid to comorbid depressive and anxiety symptoms in persons with hypertension or diabetes, but the impression for the limited research on the issue is that sub-threshold forms of depression or anxiety (i.e., episodes that do not meet full diagnostic criteria) are much more common than full-blown episodes of major depressive disorder or generalized anxiety disorder.<sup>[9]</sup> Community-based health services in China do not have the resources or personnel needed to provide sophisticated, individual-based psychopharmacological or psychotherapeutic services to these individuals, so we decided to adapt the multi-faceted 'Collaborative Care Model,'<sup>[10,11]</sup> originally developed in the United States, for use in Shanghai. This care-delivery model is targeted at all patients with hypertension or diabetes, regardless of the severity of their psychological symptoms. It aims to improve service quality by creating community-based health care teams that integrate routine surveillance and positive follow-up of patients' medical condition with assessment of their psychological status, and, if necessary, provision of social support to help the individual and his/her family members adjust to their stressful life circumstances. The current study uses a community-based design to assess the effectiveness of this comprehensive

approach to improve the psychological health, physical health, and quality of life of individuals with diabetes or hypertension.

## 2. Methods

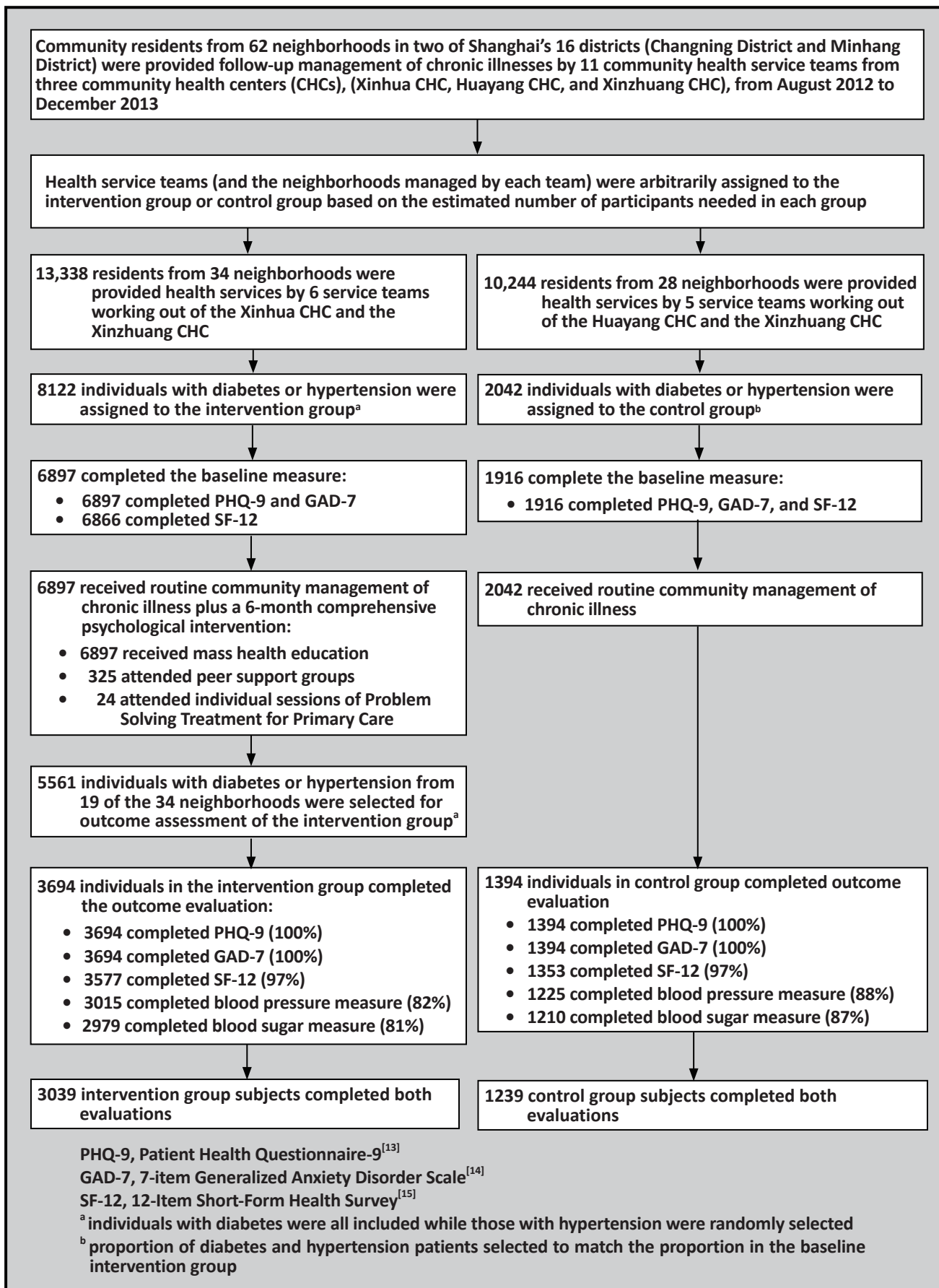
Community health services in Shanghai are provided by community health centers (CHCs) distributed throughout the municipality's 16 districts. Each community health center has a number of 'community health service teams' responsible for monitoring chronic illnesses among residents of several neighborhoods within the service area covered by the community health center. Each service team typically includes a general doctor, a nurse, and a public health clinician; among other responsibilities, they are expected to establish and maintain a registry of all residents with hypertension or diabetes in the neighborhoods; assess their blood pressure, blood sugar, and medication adherence at least four times a year; provide a full medical exam annually; refer those who need more advanced treatment; and provide related health education.

### 2.1 Sample

Study participants were community residents registered with diabetes or hypertension from three CHCs in two of Shanghai's 16 districts (the Xinhua CHC and the Huayang CHC in the Changning District and the Xinzhuang CHC in the Minhang District). As shown in Figure 1, participants came from 62 neighborhoods in the catchment areas of these three CHCs that were provided services by 11 separate community health service teams; all 17 neighborhoods serviced by four community health service teams in the Xinhua CHC; all 21 neighborhoods serviced by four community health service teams in the Huayang CHC; and 24 of the 55 neighborhoods serviced by three of the community health teams in the Xinzhuang CHC. The study inclusion criteria for residents of these communities were as follows: (a) aged 18 years or older; (b) resided in the community; (c) registered at the community health center with a diagnosis of adult-onset diabetes or primary hypertension (typically these conditions are initially diagnosed at a general hospital outpatient department and then referred back to the CHC for follow-up care); (d) no physical illness that was so severe it made it impossible to participate; (e) no mental disorder or cognitive impairment that made it impossible to participate; and (f) provided written or oral informed consent to participate in the study.

We estimated the sample size based on the prevalence of clinically significant depressive and anxiety symptoms. Assuming a relatively conservative mean baseline prevalence of 15%, in order to observe a 20% improvement (mean prevalence drop to 12%), a 3:1 ratio of intervention and control subjects, a type I error rate of 5% (i.e.,  $\alpha < 0.05$ ), a type II error rate of 80% (i.e.,  $\beta > 0.80$ ), and a 30% dropout rate over the 6 months of follow-up, there needed to be at least 4233 participants in the intervention group and 1409 participants in the control group.

Figure 1. Flowchart of the study



Based on the number of registered individuals with diabetes and hypertension in the neighborhoods in the catchment areas of the three participating CHCs, we arbitrarily assigned the 11 community health service teams from the CHCs to the intervention group or the control group such that the ratio of potential subjects in the intervention and control groups was approximately 3 to 1. As shown in Figure 1, the active psychological intervention and standard follow-up care (the intervention group) were provided to residents of 34 neighborhoods (17 neighborhoods provided services by four service teams from Xinhua CHC and 17 neighborhoods provided services by two service teams from Xinzhuang CHC) and standard follow-up care alone (the control condition) was provided to residents of 28 neighborhoods (21 neighborhoods provided services by four service teams from Huayang CHC and 7 neighborhoods provided services by one service team from Xinzhuang CHC).

Research studies indicate that the relationship between diabetes and depressive or anxiety symptoms is stronger than that between hypertension and depressive or anxiety symptoms,<sup>[12]</sup> so we included all individuals with diabetes from the intervention communities and then increased the sample to the desired size by taking a simple random sample from the residents with hypertension. Based on the ratio of diabetes and hypertension among individuals eligible for the intervention group, corresponding proportions of diabetes and hypertension patients were randomly selected from all diabetes and hypertension patients living in the control communities. After the 6-month intervention, limited resources and personnel made it impossible to redo the evaluation of all intervention group participants, so 19 of the 34 neighborhoods in the intervention group were selected (those that were most active in implementing the psychological intervention), and all persons registered with diabetes or hypertension from these neighborhoods were selected for follow-up evaluation. In the control neighborhoods, all individuals assessed at baseline were selected for the 6-month follow-up evaluation.

## 2.2 Intervention

All participants received routine management of their chronic illness. As described above, in CHCs in Shanghai this is officially supposed to include registration, complete annual physical examinations, and quarterly follow-up of community residents with adult-onset diabetes and primary hypertension. The quarterly follow-up assessments include assessment of blood pressure and fasting blood glucose, identification of sequelae or comorbid health conditions, health education about lifestyle issues, medication management, and, if necessary, referral to hospital outpatient or inpatient services for more extensive evaluation or treatment. The degree to which community residents with diabetes and hypertension participate in these CHC services varies considerably.

The community-based comprehensive psychological intervention used in this study was an adaptation of

the IMPACT model developed in the United States for use in Shanghai.<sup>[10,11]</sup> In addition to the routine management of their diabetes and/or hypertension, all intervention group subjects also received community-based education about psychological health. Some individuals in the intervention group also received additional psychological support: individual counseling was offered to individuals whose baseline scores on the Patient Health Questionnaire-9 (PHQ-9)<sup>[13]</sup> (which evaluates depressive symptoms) or the Generalized Anxiety Disorder 7-item scale (GAD-7)<sup>[14]</sup> were  $\geq 10$ ; and small-group peer support was offered to individuals whose total score on either scale was  $\geq 5$ .

The community-based mental health education component involved distributing brochures, broadcasting educational videos, and hosting lectures about psychosomatic health for individuals with chronic illnesses. The content focused on the identification and management of the symptoms of depression and anxiety, the relationship between psychological health and somatic health, and the relationship between stress and depression or anxiety.

The peer support group intervention targeted patients with diabetes or hypertension who had PHQ-9 or GAD-7 scores  $\geq 5$  but also welcomed the participation of other community members who expressed interest in the groups. This intervention involved monthly 60-90 minute meetings led by community volunteers who had received guidance from counselors. The group meetings, which typically included 9-18 individuals, focused on (a) the management of chronic diseases, (b) healthy lifestyles, (c) psychological coping skills for dealing with diabetes and hypertension, (d) knowledge about depression and anxiety, and (e) self-awareness of negative emotions. In addition to the transmission of crucial information, the meetings also provided emotional and social support to the participants, something that previous research has shown to reduce depressive symptoms and improve the control of diabetes and hypertension.<sup>[15]</sup>

The individual intervention targeted individuals whose PHQ-9 or GAD-7 score was  $\geq 10$ . Counselors (individuals who had a nationally approved Level-2 counseling certificate) provided one 60-minute and six 30-minute sessions of Problem Solving Treatment for Primary Care (PST-PC)<sup>[16]</sup> to each individual. The counseling focused on alleviating symptoms of depression and anxiety by assisting these individuals to become more self-aware, to learn how to analyze and deal with their problems, to decrease their feelings of frustration, and to increase their feelings of control over their lives. PST has been found to be effective in the management of emotional problems among patients treated at community health centers.<sup>[16]</sup>

The three components of this community-based intervention in the 34 neighborhoods was collaboratively coordinated and provided by 391 individuals, including local administrators, community clinicians, community public health workers, counselors, and volunteers. All individuals who provided each of the three components of the intervention received

appropriate training before implementing the intervention. We ensured that the group leaders and counselors grasped related skills through the introduction of learning theories, the illustration of examples, discussion, and role-play exercises. During the intervention process, peer support leaders and the counselors also routinely received professional supervision in order to identify and address any problems in a timely manner.

### 2.3 Measures

At baseline all participants completed a detailed demographic and clinical status form, the PHQ-9<sup>[13]</sup> to assess the severity of depression, the GAD-7<sup>[14]</sup> to assess the severity of anxiety, and the 12-Item Short-Form Health Survey (SF-12)<sup>[17]</sup> to assess quality of life. Six months later the PHQ-9, GAD-7, and SF-12 were re-administered, and participants were asked to classify the control of their diabetes and/or hypertension as 'very stable', 'stable', or 'unstable'.

Demographic and clinical variables considered included age, gender, marital status, level of education, employment status, age of onset of current illness, course of illness, presence of physical sequelae of diabetes or hypertension, and frequency of hospital-based treatment (as outpatient or inpatient) in the prior 6 months.

The PHQ-9 and GAD-7 are widely used self-completion scales with good reliability and validity<sup>[18,19]</sup> which assess the frequency of specific depressive and anxiety symptoms over the prior two weeks. The items on both scales are rated on 4-point Likert scales (0='never' to 3='almost every day'), so the total score for 9-item PHQ-9 ranges from 0 to 27 and that for 7-item GAD-7 ranges from 0 to 21, with higher scores representing more severe depressive or anxiety symptoms. The PHQ-9 total score is classified as follows:<sup>[18]</sup> 0 to 4, 'no depression'; 5 to 9, 'mild depression'; 10 to 14, 'moderate depression'; 15 to 19, 'moderate to severe depression'; 20 or above, 'severe depression'. The GAD-7 total score is classified as follows:<sup>[19]</sup> 0 to 4, 'no anxiety'; 5 to 9, 'mild anxiety'; 10 to 14, 'moderate anxiety'; 15 or above, 'severe anxiety'.

Research has shown that the SF-12<sup>[17]</sup> is a valid measure of quality of life in the general Chinese population.<sup>[20]</sup> We use two components from the scale in the current analysis: the Mental Component Summary (MCS) score and the Physical Component Summary (PCS) score. These scores are based on weighting responses to all 12 items, with higher scores indicating better quality of life.

### 2.5 Statistical analysis

We used EpiData 3.1 (The EpiData Association, Odense, Denmark) to input and manage the data and used SPSS 17.0 (SPSS Inc., Chicago, IL, USA) to analyze the data. Categorical data were compared using Chi-square tests, continuous data were analyzed using parametric or non-parametric tests depending on whether or not the data was distributed normally.

The main analysis was based on the subset of participants who completed both the baseline and 6-month evaluations. Six subgroups of respondents were identified according to the baseline results on the PHQ-9 and GAD-7: (1) those with PHQ-9  $\geq 5$ ; (2) those with GAD-7  $\geq 5$ ; (3) those with PHQ-9  $\geq 10$ ; (4) those with GAD-7  $\geq 10$ ; (5) those with PHQ-9 or GAD-7  $\geq 5$ ; and (6) those with PHQ-9 or GAD-7  $\geq 10$ .

## 3. Results

### 3.1 Completion status

There were 10,164 individuals with diabetes or hypertension registered in the 62 participating communities and 8813 of them (86.7%) completed the baseline evaluation; 6897 of the 8122 (84.9%) residents in the intervention group neighborhoods with diabetes or hypertension completed the baseline assessment and 1916 of the 2042 (93.9%) residents in the control group neighborhoods with diabetes or hypertension completed the baseline assessment. The main reasons for failure to participate in the study were failure to meet the inclusion criteria, refusal to participate, and difficulty of access to the CHC (some registered residents at the CHCs actually live elsewhere). Comparison of the 1351 who did not participate with the 8813 who did participate found no significant difference by gender (46.7% v. 45.2% male, respectively,  $X^2=1.02$ ,  $p=0.314$ ) or in the mean (sd) age (70.0 [10.2] v. 69.6 [10.3] years, respectively,  $t=1.14$ ,  $p=0.253$ ).

Only 19 of the 34 intervention communities participated in the 6-month outcome evaluation, but all 28 control communities participated in the 6-month follow-up evaluation. In total 7603 individuals were selected to participate in the outcome evaluation and 5088 of them (66.9%) completed the evaluation; in the intervention group 3694 of the 5561 (66.4%) selected individuals completed the outcome assessment and in the control group 1394 of the 2042 (68.3%) selected individuals completed the outcome assessment.

As shown in Figure 1, 3039 participants in the intervention group and 1239 in the control group completed both the baseline and the outcome evaluations.

### 3.2 Comparison of individuals who do and do not complete both evaluations

Table 1 compares the demographic and clinical characteristics of individuals in the control group and the intervention group who only completed the baseline evaluation with the characteristics of individuals from the two groups who completed both the baseline and 6-month follow-up evaluations (and thus, were included in the outcome assessment for the intervention). In the control group, the mean (sd) age of the 1239 individuals who completed both evaluations was not significantly different from that of the 677 individuals who only completed the baseline assessment (70.4 [10.3] v. 69.6 [10.1] years, respectively,  $t=1.08$ ,  $p=0.279$ ), but individuals who

**Table 1. Comparison of demographic characteristics and illness characteristics in the intervention group and the control group between respondents who only completed the baseline assessment and those who completed both the baseline and the 6-month outcome assessment<sup>a</sup>**

characteristic	control group			intervention group			
	only completed baseline assessment (n=677)	completed both assessments (n=1239)	$\chi^2$ (p-value)	only completed baseline assessment (n=3858)	completed both assessments (n=3039)	$\chi^2$ (p-value)	
	n (%)	n (%)		n (%)	n (%)		
age group	<65 years	215 (31.8)	374 (30.2)	1.25	1302 (33.7)	1020 (33.6)	0.03
	65- 80	343 (50.7)	623 (50.3)	(0.535)	1851 (48.0)	1464 (48.2)	(0.985)
	>80	119 (17.6)	242 (19.5)		705 (18.3)	555 (18.3)	
gender	male	302 (44.6)	564 (45.5)	0.15	1770 (45.9)	1351 (44.5)	1.39
	female	375 (55.4)	675 (54.5)	(0.701)	2088 (54.1)	1688 (55.5)	(0.238)
employment status	retired	611 (90.4)	1138 (91.9)	5.37	3488 (90.4)	2748 (90.5)	0.002
	working/studying	35 (5.2)	69 (5.6)	(0.068)	249 (6.5)	196 (6.5)	(0.999)
	other	30 (4.4)	31 (2.5)		120 (3.1)	94 (3.1)	
occupation	institution manager	117 (17.3)	199 (16.1)	8.84	605 (15.7)	536 (17.6)	18.60
	professional/technician	170 (25.1)	258 (20.8)	(0.065)	951 (24.7)	824 (27.1)	<b>(0.001)</b>
	general worker	105 (15.5)	223 (18.0)		757 (19.6)	502 (16.5)	
	laborer	263 (38.9)	532 (42.9)		1415 (36.7)	1093 (36.0)	
	other	21 (3.1)	27 (2.2)		125 (3.2)	83 (2.7)	
educational level	illiterate	66 (9.8)	77 (6.2)	8.10	217 (5.6)	152 (5.0)	12.93
	elementary school	111 (16.4)	213 (17.2)	<b>(0.044)</b>	595 (15.4)	455 (15.0)	<b>(0.005)</b>
	middle school	376 (55.6)	723 (58.4)		2292 (59.4)	1732 (57.0)	
	college degree	123 (18.2)	225 (18.2)		752 (19.5)	698 (23.0)	
marital status	never married	9 (1.3)	17 (1.4)	2.47	45 (1.2)	22 (0.7)	7.56
	married	539 (79.9)	1023 (82.6)	(0.291)	3280 (85.1)	2544 (83.7)	<b>(0.023)</b>
	divorced/widowed	127 (18.8)	198 (16.0)		531 (13.8)	473 (15.6)	
illness	only hypertension	396 (58.5)	674 (54.4)	3.18	2341 (60.7)	2122 (69.8)	<b>69.56</b>
	only diabetes	100 (14.8)	192 (15.5)	(0.203)	449 (11.6)	224 (7.4)	<b>(&lt;0.001)</b>
	hypertension + diabetes	181 (26.7)	373 (30.1)		1068 (27.7)	693 (22.8)	
sequelae of diabetes or hypertension	0 no sequelae	419 (61.9)	783 (63.2)	1.19	2590 (67.2)	2143 (70.5)	10.80
	1 sequela	166 (24.5)	277 (22.4)	(0.551)	771 (20.0)	573 (18.9)	<b>(0.005)</b>
	2+ sequelae	92 (13.6)	178 (14.4)		493 (12.8)	322 (10.6)	
years duration of illness	<6 years	159 (23.5)	285 (23.0)	0.102	887 (24.2)	746 (25.3)	11.77
	6-10 years	172 (25.4)	322 (26.0)	(0.950)	1024 (27.9)	712 (24.2)	<b>(0.003)</b>
	≥11 years	345 (51.0)	631 (51.0)		1758 (47.9)	1487 (50.5)	
hospital-based treatments in the last 6 months	0 hospital visits	466 (69.2)	860 (69.6)	7.85	2940 (76.6)	2322 (76.9)	6.82
	1-2 hospital visits	49 (7.3)	131 (10.6)	<b>(0.020)</b>	320 (8.3)	205 (6.8)	<b>(0.033)</b>
	3+ hospital visits	158 (23.5)	245 (19.8)		580 (15.1)	492(16.3)	

<sup>a</sup> MISSING DATA FOR RESPONDENTS IN THE CONTROL GROUP: for those who only completed the baseline assessment, there were 1 missing data in employment status, 1 in occupation, 1 in educational level, 2 in marital status, 1 in years duration of illness, and 4 in hospital-based treatments in the last 6 months; for those who completed both assessments, there were 1 missing data in employment status, 1 in educational level, 1 in marital status, 1 in sequelae of diabetes or hypertension, 1 in years duration of illness, and 3 in hospital-based treatments in the last 6 months;

MISSING DATA FOR RESPONDENTS IN THE INTERVENTION GROUP: for those who only completed the baseline assessment, there were 1 missing data in employment status, 5 in occupation, 2 in education level, 2 in marital status, 4 in sequelae of diabetes or hypertension, 189 in years duration of illness, and 18 in hospital-based treatments in the last 6 months; for those who completed both assessments, there were 1 missing data in employment status, 1 in occupation, 2 in education level, 1 in sequelae of diabetes or hypertension, 94 in years duration of illness, and 20 in hospital-based treatments in the last 6 months

completed both assessments had a higher level of education and had made fewer hospital visits for treatment of their diabetes and/or hypertension in the prior 6 months than individuals who only completed the baseline assessment. In the intervention group, there was also no significant difference in age between the 3039 individuals who completed both assessments compared to that of the 3858 individuals who only completed the baseline assessment (69.4 [10.3] v. 69.4 [10.3] years, respectively,  $t=0.11$ ,  $p=0.916$ ), but several other variables were significantly different between the two subgroups of individuals living in the intervention group neighborhoods: compared to individuals who only completed the baseline assessment, those who completed both assessments were more likely to be professionals or managers, had a higher level of education, were more likely to be divorced or widowed, were more likely to only have hypertension, were less likely to have complications (sequelae) of diabetes or hypertension, had a longer duration of illness, and were more likely to have made multiple hospital visits for the management of their illness over the prior 6 months.

Comparison of the baseline results for the four primary outcome measures between those who only completed the baseline evaluation and those who completed both evaluations was as follows. In the control group the mean (sd) PHQ-9 for the 1239 individuals who completed both evaluations and the 677 individuals who only completed the baseline evaluation were 2.39 (3.42) and 2.26 (3.60), respectively ( $t=-0.82$ ,  $p=0.414$ ); the corresponding results for the GAD-7 were 1.16 (2.36) and 1.12 (2.59) ( $t=-0.37$ ,  $p=0.710$ ); those for the PCS of the SF-12 were 45.0 (8.9) and 45.1 (9.5), ( $t=0.30$ ,  $p=0.765$ ); and those for the MCS of the SF-12 were 54.4 (8.8) and 55.2 (9.1) ( $t=1.75$ ,  $p=0.081$ ). In the intervention group the mean (sd) PHQ-9 for the 3039 individuals who completed both evaluations and the 3858 individuals who only completed the baseline evaluation were 1.90 (3.17) and 2.18 (3.45), respectively ( $t=3.46$ ,  $p=0.001$ ); the corresponding results for the GAD-7 were 0.88 (2.11) and 1.10 (2.54) ( $t=3.89$ ,  $p<0.001$ ); those for the PCS of the SF-12 were 46.2 (8.4) and 45.5 (9.0) ( $t=-3.52$ ,  $p<0.001$ ); and those for the MCS of the SF-12 were 55.5 (8.3) and 54.1 (8.4), respectively ( $t=-7.02$ ,  $p<0.001$ ).

### 3.3 Comparison of characteristics of the two groups at baseline and after both assessments

Table 2 shows the comparison of the baseline demographic and clinical variables for individuals who completed the baseline evaluation in the intervention and control groups and for individuals who completed both the baseline and 6-month follow-up evaluations in the two groups. At baseline, there were no significant differences between the intervention and control groups by gender, employment status, or duration of illness, but, given the very large sample, several relatively small differences between the groups in other variables were statistically significant. For example, the mean (sd)

age in the control group was 70.5 (10.2) years versus 69.7 (10.3) years in the intervention group; this minor difference in mean age of 0.8 years was statistically significant ( $t=9.18$ ,  $p=0.002$ ). As shown in the table, compared to control group participants, intervention group participants were also significantly less likely to be manual laborers (36.4% v. 41.5%), more likely to have a college education (21.0% v. 18.2%), more likely to be married (84.5% v. 81.7%), much more likely to only have hypertension (64.7% v. 55.8%), less likely to have one or more sequelae of diabetes or hypertension (31.3% v. 37.2%), and less likely to have made one or more hospital visits (as outpatient or inpatient) to manage their illness in the prior 6 months (23.3% v. 30.5%).

Most of the differences between the intervention and control groups seen at the baseline assessment persisted in the subgroup of individuals who completed both baseline and follow-up assessments. Compared to control group participants, intervention group participants were less likely to be manual laborers, more likely to have a college education, much more likely to only have hypertension, less likely to have one or more sequelae of diabetes or hypertension, and less likely to have made one or more hospital visits to manage their illness in the prior 6 months. Intervention group participants who completed both evaluations were also younger than control group participants who completed both evaluations (69.4 [10.2] v. 70.4 [10.3] years, respectively,  $t=2.97$ ,  $p=0.003$ ).

### 3.4 Prevalence of depressive and anxiety symptoms at baseline

Combining the results of all 8813 community residents with hypertension or diabetes who completed the baseline assessment with PHQ-9 and the GAD-7 from both the intervention and control groups, the prevalence of the six categories of depressive and anxiety conditions were as follows: 14.7% (1292/8813) had mild or more severe depressive symptoms (PHQ-9  $\geq 5$ ); 7.0% (613/8813) had mild or more severe anxiety symptoms (GAD-7  $\geq 5$ ); 16.0% (1409/8813) had mild or more severe depressive or anxiety symptoms (PHQ-9 or GAD-7  $\geq 5$ ); 3.9% (344/8813) had moderate or severe depressive symptoms (PHQ-9  $\geq 10$ ); 1.6% (140/8813) had moderate or severe anxiety symptoms (GAD-7  $\geq 10$ ); and 4.2% (369/8813) had moderate or severe depressive or anxiety symptoms (PHQ-9 or GAD-7  $\geq 10$ ).

The 8813 individuals who completed the baseline assessments included 5533 with primary hypertension only, 965 with adult-onset diabetes only, and 2315 with both hypertension and diabetes. The prevalence of mild or more severe depressive or anxiety symptoms (PHQ-9 or GAD-7  $\geq 5$ ) in these three groups of respondents was 13.4%, 17.7%, and 21.3%, respectively ( $\chi^2=78.11$ ,  $df=2$ ,  $p<0.001$ ). The prevalence of moderate or severe depressive or anxiety symptoms (PHQ-9 or GAD-7  $\geq 10$ ) in the three groups of respondents was 3.3%, 4.9%, and 6.0%, respectively ( $\chi^2=29.52$ ,  $df=2$ ,  $p<0.001$ ).

**Table 2. Comparison of demographic characteristics and illness characteristics between the intervention group and the control group at baseline and among individuals who completed the baseline and the 6-month assessments<sup>a</sup>**

characteristic	completed baseline assessment			completed both assessments			
	control group (n=1916)	intervention group (n=6897)	$\chi^2$	control group (n=1239)	intervention group (n=3039)	$\chi^2$	
	n (%)	n (%)	(p-value)	n (%)	n (%)	(p-value)	
age group	<65 years	589 (30.7)	2322 (33.7)	5.86	374 (30.2)	1020 (33.6)	4.65
	65- 80	966 (50.4)	3315 (48.1)	(0.053)	623 (50.3)	1464 (48.2)	(0.098)
	>80	361 (18.8)	1260 (18.3)		242 (19.5)	555 (18.3)	
gender	male	866 (45.2)	3121 (45.3)	0.002	564 (45.5)	1351 (44.5)	0.40
	female	1050 (54.8)	3776 (54.7)	(0.967)	675 (54.5)	1688 (55.5)	(0.525)
employment status	retired	1749 (91.4)	6236 (90.4)	2.68	1138 (91.9)	2748 (90.5)	2.35
	working/studying	104 (5.4)	445 (6.5)	(0.262)	69 (5.6)	196 (6.5)	(0.309)
	other	61 (3.2)	214 (3.1)		31 (2.5)	94 (3.1)	
occupation	institution manager	316 (16.5)	1141 (16.6)	19.87	199 (16.1)	536 (17.6)	28.48
	professional/technician	428 (22.3)	1775 (25.8)	<b>(&lt;0.001)</b>	258 (20.8)	824 (27.1)	<b>(&lt;0.001)</b>
	general worker	328 (17.1)	1259 (18.3)		223 (18.0)	502 (16.5)	
	laborer	795 (41.5)	2508 (36.4)		532 (42.9)	1093 (36.0)	
	other	48 (2.5)	208 (3.0)		27 (2.2)	83 (2.7)	
educational level	illiterate	143 (7.5)	369 (5.4)	20.53	77 (6.2)	152 (5.0)	14.91
	elementary school	324 (16.9)	1050 (15.2)	<b>(&lt;0.001)</b>	213 (17.2)	455 (15.0)	<b>(0.002)</b>
	middle school	1099 (57.4)	4024 (58.4)		723 (58.4)	1732 (57.0)	
	college degree	348 (18.2)	1450 (21.0)		225 (18.2)	698 (23.0)	
marital status	never married	26 (1.4)	67 (1.0)	9.39	17 (1.4)	22 (0.7)	4.29
	married	1562 (81.7)	5824 (84.5)	<b>(0.009)</b>	1023 (82.6)	2544 (83.7)	(0.117)
	divorced/widowed	325 (16.9)	1004 (14.5)		198 (16.0)	473 (15.6)	
Illness	only hypertension	1070 (55.8)	4463 (64.7)	66.45	674 (54.4)	2122 (69.8)	110.64
	only diabetes	292 (15.2)	673 (9.8)	<b>(&lt;0.001)</b>	192 (15.5)	224 (7.4)	<b>(&lt;0.001)</b>
	hypertension + diabetes	554 (28.9)	1761 (25.5)		373 (30.1)	693 (22.8)	
sequelae of diabetes or hypertension	0 no sequelae	1,202 (62.8)	4,733 (68.7)	23.79	783 (63.2)	2143 (70.5)	23.04
	1 sequela	443 (23.1)	1,344 (19.5)	<b>(&lt;0.001)</b>	277 (22.4)	573 (18.9)	<b>(&lt;0.001)</b>
	2+ sequelae	270 (14.1)	815 (11.8)		178 (14.4)	322 (10.6)	
years duration of illness	<6 years	444 (23.2)	1633 (24.7)	2.58	285 (23.0)	746 (25.3)	3.11
	6-10 years	494 (25.8)	1736 (26.2)	(0.275)	322 (26.0)	712 (24.2)	(0.211)
	≥11 years	976 (51.0)	3245 (49.1)		631 (51.0)	1487 (50.5)	
hospital-based treatments in the last 6 months	0 hospital visits	1326 (69.5)	5262 (76.7)	42.99	860 (69.6)	2322 (76.9)	28.71
	1-2 hospital visits	180 (9.4)	525 (7.7)	<b>(&lt;0.001)</b>	131 (10.6)	205 (6.8)	<b>(&lt;0.001)</b>
	3+ hospital visits	403 (21.1)	1072 (15.6)		245 (19.8)	492(16.3)	

<sup>a</sup> MISSING DATA FOR ALL RESPONDENTS WHO COMPLETED THE BASELINE ASSESSMENT; in the control group, there were 2 missing data in employment status, 1 in occupation, 2 in educational level, 3 in marital status, 1 in sequelae of diabetes or hypertension, 2 in years duration of illness, and 7 in hospital-based treatments in the last 6 months; and for those in the intervention group there were 2 missing data in employment status, 6 in occupation, 4 in education level, 2 in marital status, 5 in sequelae of diabetes or hypertension, 283 in years duration of illness, and 38 in hospital-based treatments in the last 6 months

MISSING DATA FOR RESPONDENTS WHO COMPLETED BOTH ASSESSMENTS; in the control group, there were 1 missing data in employment status, 1 in educational level, 1 in marital status, 1 in sequelae of diabetes or hypertension, 1 in years duration of illness, and 3 in hospital-based treatments in the last 6 months; and for those in the intervention group there were 1 missing data in employment status, 1 in occupation, 2 in education level, 1 in sequelae of diabetes or hypertension, 94 in years duration of illness, and 20 in hospital-based treatments in the last 6 months



### 3.5 Fidelity of the implementation of the community-based psychological intervention

In the intervention group almost all individuals with diabetes or hypertension were exposed to the mass education effort. We delivered 20,000 brochures and 5,000 DVDs with psycho-educational content to homes in the intervention neighborhoods. Each DVD had two to eight lectures. The DVDs were also broadcast for a total of 514 days in community venues for a total time of approximately 4000 hours.

A total of 325 individuals participated in the small-group peer support intervention, that is, only 30.8% of the 1055 participants who were eligible (baseline PHQ-9 or GAD-7 score  $\geq 5$ ) for this intervention. They were divided into 28 peer support groups that met a total of 575 times. The mean (sd) attendance by each of these participants was 17.3 (8.6) times.

A total of 24 individuals received individualized sessions of PST, that is, only 8.9% of the 269 participants who were eligible (baseline PHQ-9 or GAD-7 score  $\geq 10$ ) for this intervention. In total, 83 individual counseling sessions were held; the mean (sd) frequency of counseling sessions for these individuals was 4.3 (2.4) times.

### 3.6 Evaluation of the outcome of the intervention

The results of the intervention are shown in Tables 3 and 4. Table 3 compares the continuous outcome measures, that is, the total scores for the PHQ-9, GAD-7, and the Physical Component Summary (PCS) and Mental

Component Summary (MCS) scores of the SF-12. In the control group, the self-reported level of depression and anxiety became more severe over the 6-month follow-up, the PCS score did not change significantly, and the MCS score got worse. Over the same period in the intervention group, the level of depression did not change significantly, the level of anxiety improved, the PCS score did not change significantly, and the MCS score improved significantly. At both baseline and at the 6-month follow-up assessment the intervention group had significantly less severe depression, less severe anxiety, and better PCS and MCS scores than the control group. After adjusting for the baseline differences of the measures and for the demographic variables that were significantly different between the groups at baseline, at the 6-month follow-up the intervention group still had significantly less severe depression, significantly less severe anxiety, and a significantly higher MCS scores than the control group.

Table 4 compares the dichotomous outcome measures between the groups. Among the 1239 individuals who completed both assessments in the control group and the 3039 individuals who completed both assessments in the intervention group, the classification of the subtypes of depressive and anxiety symptoms at baseline was as follows: (a) the prevalence of mild or more severe depressive symptoms (PHQ-9  $\geq 5$ ) was 17.6% versus 12.5%, respectively; (b) the prevalence of moderate or severe depressive symptoms (PHQ-9  $\geq 10$ ) was 4.6% versus 5.6%, respectively; (c) the prevalence of mild or more severe anxiety symptoms (GAD-7  $\geq 5$ ) was 8.1% versus 3.5%,

**Table 3. Comparison of mean (sd) results in the intervention group subjects and control group subjects who completed both the baseline and the 6-month follow-up assessments**

scale	control group				intervention group				comparison of control and intervention groups		
	n	baseline	at 6 months	paired t-test (p)	n	baseline	at 6 months	paired t-test (p)	at baseline t-test (p)	at 6 months t-test (p)	at 6 months F-test (p) <sup>a</sup>
PHQ-9	1239	2.39 (3.42)	3.04 (3.44)	5.64 ( <b>&lt;0.001</b> )	3039	1.90 (3.17)	1.81 (3.25)	1.30 (0.194)	4.36 ( <b>&lt;0.001</b> )	10.81 ( <b>&lt;0.001</b> )	9.98 ( <b>&lt;0.001</b> )
GAD-7	1239	1.16 (2.36)	1.74 (2.58)	6.67 ( <b>&lt;0.001</b> )	3039	0.88 (2.11)	0.73 (1.96)	3.41 ( <b>0.001</b> )	3.65 ( <b>&lt;0.001</b> )	12.48 ( <b>&lt;0.001</b> )	12.85 ( <b>&lt;0.001</b> )
SF-12-PCS	1207	44.9 (8.7)	45.1 (8.0)	0.44 (0.664)	2954	46.2 (8.4)	46.0 (8.5)	1.55 (0.121)	4.26 ( <b>&lt;0.001</b> )	3.26 ( <b>0.001</b> )	1.03 (0.306)
SF-12-MCS	1207	54.4 (8.8)	51.9 (8.5)	8.03 ( <b>&lt;0.001</b> )	2954	55.6 (8.3)	56.5 (7.5)	5.28 ( <b>&lt;0.001</b> )	3.87 ( <b>&lt;0.001</b> )	16.46 ( <b>&lt;0.001</b> )	16.13 ( <b>&lt;0.001</b> )

PHQ-9, 9-item Patient Health Questionnaire<sup>[13]</sup>

GAD-7, 7-item General Anxiety Disorder scale<sup>[14]</sup>

SF-12-PCS, Physical Component Summary score computed by weighting items of the 12-item Short Form Health Survey<sup>[15]</sup>

SF-12-MCS, Mental Component Summary score computed by weighting items of the 12-item Short Form Health Survey<sup>[15]</sup>

<sup>a</sup> F-test for analysis of covariance that controls for baseline value and for demographic variables that were different at baseline (i.e., occupation, occurrence of sequelae, and hospital-based treatment in prior 6 months).

**Table 4. Comparison of proportions of respondents with mild or or more severe depression or anxiety (PHQ-9 or GAD-7 total score  $\geq 5$ ) or moderate or severe depression or anxiety (PHQ-9 or GAD-7 total score  $\geq 10$ ) among intervention group and control group respondents who completed both the baseline and 6-month follow-up assessments**

scale	control group				intervention group				comparison of control and intervention groups		
	n	baseline n (%)	6 months n (%)	McNemar test (p)	n	baseline n (%)	6 months n (%)	McNemar test (p)	at baseline OR (95% CI)	at 6 months OR (95% CI)	at 6 months OR (95% CI) <sup>a</sup>
PHQ-9 $\geq 5$	1239	218 (17.6)	322 (26.0)	32.00 (<0.001)	3039	379 (12.5)	332 (10.9)	4.29 (0.043)	0.67 (0.56-0.80)	0.35 (0.29-0.41)	0.36 (0.30-0.43)
GAD-7 $\geq 5$	1239	100 (8.1)	167 (13.5)	22.11 (<0.001)	3039	106 (3.5)	120 (3.9)	0.90 (0.343)	0.68 (0.53-0.88)	0.34 (0.27-0.42)	0.34 (0.27-0.43)
PHQ-9 $\geq 10$	1239	57 (4.6)	83 (6.7)	5.30 (0.021)	3039	171 (5.6)	151 (5.0)	1.38 (0.240)	0.75 (0.54-1.04)	0.57 (0.43-0.76)	0.60 (0.45-0.81)
GAD-7 $\geq 10$	1239	17 (1.4)	22 (1.8)	0.43 (0.511)	3039	36 (1.2)	29 (1.0)	0.68 (0.410)	0.86 (0.48-1.54)	0.53 (0.31-0.93)	0.60 (0.34-1.07)
PHQ-9 or GAD-7 $\geq 5$	1239	236 (19.0)	336 (27.1)	28.74 (<0.001)	3039	416 (13.7)	345 (11.4)	9.42 (<0.001)	0.67 (0.57-0.80)	0.34 (0.29-0.41)	0.36 (0.30-0.43)
PHQ-9 or GAD-7 $\geq 10$	1239	60 (4.8)	88 (7.1)	5.79 (0.016)	3039	111 (3.7)	122 (4.0)	0.51 (0.474)	0.74 (0.54-1.03)	0.55 (0.41-0.73)	0.58 (0.43-0.78)
self-report of unstable blood pressure control	1225	---	37 (3.0)	---	3015	---	101 (3.3)	---	---	0.90 (0.61-1.32)	---
self-report of unstable diabetes control	1210	---	59 (4.9)	---	2979	---	107 (3.6)	---	---	1.38 (0.99-1.90)	---

PHQ-9, 9-item Patient Health Questionnaire<sup>[13]</sup>  
 GAD-7, 7-item General Anxiety Disorder scale<sup>[14]</sup>  
 SF-12-PCS, Physical Component Score of 12-item Short Form Health Survey<sup>[15]</sup>  
 SF-12-MORCS, Mental Component Score of 12-item Short Form Health Survey<sup>[15]</sup>  
 OR, Odds Ratio  
 95% CI, 95 percent Confidence Interval

<sup>a</sup> Odds ratio adjusted for baseline values value and for demographic variables that were different at baseline (i.e., occupation, occurrence of sequelae, and hospital-based treatment in prior 6 months,).

respectively; (d) the prevalence of moderate or severe anxiety symptoms (GAD-7  $\geq 10$ ) was 1.4% versus 1.2%, respectively; (e) the prevalence of mild or more severe depressive or anxiety symptoms (PHQ-9 or GAD-7  $\geq 5$ ) was 19.0% versus 13.7%, respectively; and (f) the prevalence of moderate or severe depressive or anxiety symptoms (PHQ-9 or GAD-7  $\geq 10$ ) was 4.8% versus 3.7%, respectively. At baseline the prevalence of mild (or more severe) depressive symptoms, mild anxiety symptoms, and mild depressive or anxiety symptoms was significantly greater in the control group than in the intervention group.

In the control group, the prevalence of mild or more severe depressive symptoms, mild or more severe anxiety symptoms, moderate or severe depressive symptoms, and mild or moderate depressive or anxiety symptoms *increased* significantly over the

6-month follow-up period. Over the same period in the intervention group the prevalence of mild or more severe depressive symptoms decreased significantly and the prevalence of mild or more severe depressive or anxiety symptoms also decreased significantly. The prevalence of all six measures was significantly lower in the intervention group than in the control group at the 6-month follow-up assessment. Five of the 6 measures (with the exception of the prevalence of moderate or severe anxiety symptoms) remained significantly different between groups even after adjusting for the baseline prevalence and for demographic and clinical variables that were significantly different between the groups at baseline.

At the 6-month follow-up the self-reported rate of unstable hypertension and unstable diabetes was not significantly different between individuals in the control and intervention groups.

## 4. Discussion

### 4.1 Main findings

This 6-month community-based study was a large-scale effort aimed at assessing the feasibility of reducing the severity of depressive and anxiety symptoms of individuals with diabetes or hypertension in an environment where mental health personnel are extremely limited. At baseline the prevalence of self-reported mild or more severe depressive or anxiety symptoms (assessed using the PHQ-9 and the GAD-7) in 8813 community residents receiving treatment for diabetes or hypertension was 16% and the prevalence of moderate or severe depressive or anxiety symptoms (i.e., clinically significant symptoms) was 4%. We encountered substantial difficulties in implementing such a large intervention project (described below), but the overall outcome – based on the self-report of participants – indicates that the multi-component intervention substantially reduced the severity of both depressive and anxiety symptoms in individuals receiving routine care for diabetes or hypertension. We also found that the intervention was associated with an improvement in the mental health component of quality of life (assessed by the Mental Component Summary score of the SF-12), but not in the physical health component of quality of life (assessed by the Physical Component Summary score of the SF-12) or in the self-reported rates of uncontrolled diabetes or hypertension.

Our results about changes in depressive and anxiety symptoms associated with the psychological intervention (primarily community-based mental health education campaign) are largely consistent with results from other countries. The rapid epidemiological transition (and aging of the population) in high-income countries and many low- and middle-income countries is resulting in dramatic increases in the prevalence of non-communicable diseases such as diabetes and hypertension, a trend that is particularly evident in China. One potential approach to reducing the health burden of such conditions in high-income countries is to manage the psychological symptoms that often co-exist with these chronic physical conditions.<sup>[21]</sup> The results of studies in this area are not entirely consistent, but the weight of the evidence supports the value of alleviating symptoms of depression and anxiety in individuals with chronic medical conditions.<sup>[22,23]</sup> Based on these findings, international practice guidelines, such as those proposed by the International Diabetes Federation (IDF),<sup>[24]</sup> stress the need to address psychological disorders in the management of individuals with diabetes.

Previous studies in the international and Chinese literature suggest that psychological interventions can significantly improve the indicators of somatic health such as blood pressure<sup>[23,25]</sup> and blood sugar levels,<sup>[23,26]</sup> but the conclusions from systematic reviews of these studies are inconclusive.<sup>[6,27-29]</sup> In this study we did not find differences in the change in the clinical status of diabetes or hypertension between the intervention

and control groups, but our assessment of the somatic effects of the intervention were limited to self-reports of having ‘unstable’ hypertension or ‘unstable’ control of blood sugar levels, and to self-reports of the Physical Component Summary score of the SF-12, so the study may not have been sensitive to changes in these physical conditions. Previous studies about the correlation of objective measures of blood pressure and blood sugar levels with self-reports of blood pressure monitoring<sup>[30]</sup> and self-reports of blood sugar monitoring<sup>[31]</sup> show variable results, so basing a decision about the effectiveness of an intervention on such self-report measures is probably unwise. At the very least, future studies need to include assessment of baseline and post-intervention blood pressure and fasting blood glucose levels.

Depression, anxiety, and chronic illness all negatively affect an individuals’ quality of life. Several authors<sup>[23,32]</sup> suggest that psychological interventions that alleviate symptoms of depression or anxiety in individuals with chronic medical conditions can simultaneously improve the individuals’ quality of life. The present study found that our community-based psychological intervention was associated with improvement in the psychological component of quality of life (the MCS score for the SF-12) but not in the somatic component of quality of life (the PCS score of the SF-12). This result is consistent with the findings of a systematic review of collaborative care<sup>[21]</sup> and with a study on the treatment of depression in individuals with coronary artery disease.<sup>[5]</sup>

### 4.2 Limitations

This study has several major limitations that should be considered when interpreting the results. We included community residents registered at three community health centers (CHCs) in Shanghai with diabetes or hypertension, but the included CHCs may not be representative of all CHCs in Shanghai, and, more importantly, the management rates of hypertension and diabetes in Shanghai communities is only about 40%,<sup>[33]</sup> so there may be a selection bias which limits the generalization of the results. Other factors that affect the representativeness of the sample on which the assessment of the outcome of the intervention was based (i.e., individuals who completed both the baseline and follow-up evaluations) included: (a) relatively high dropout rates for both the intervention group (56%) and the control group (35%); (b) significant differences in the demographic characteristics, clinical characteristics, and baseline results for the outcome variables of interest between those who do and do not complete the study; and (c) restriction of the outcome assessment for the intervention group to the 19 neighborhoods (out of 34 neighborhoods) where the intervention was considered most effective. The initial intention to balance the proportion of participants with hypertension and diabetes in the intervention and control groups was not effective: the much higher

proportion of intervention group participants than control group participants with hypertension (without comorbid diabetes) who completed the study (70% v. 54%) is particularly concerning because most reports suggest that hypertension is less likely to be associated with depressive and anxiety symptoms than diabetes.<sup>[12]</sup>

Another major problem with the study was the low participation rate in the small-group peer support effort (31% of eligible individuals participated) and in the PST counseling component of the intervention (9% of eligible individuals participated). Only 349 of the 6897 (5%) individuals in the intervention neighborhoods who completed the baseline assessment participated in these components of the intervention, so it is unlikely that these components of the intervention had much effect on the overall results; thus the outcome assessment primarily reflected the outcome of the mass education campaign. Potential reasons for the low participation in these components of the intervention include: (a) patients were invited to participate by the community clinicians, some of whom were unable or unwilling to take the time to explain the potential value of the psychological intervention to the target recipients; (b) concerns about privacy, confidentiality, and the stigma of being labeled as 'mentally ill' limited participants' willingness to join peer support groups; and (c) the volunteer counselors who provided PST were unknown to the participants and, moreover, had little experience in working with elderly patients.

Other limitations of the study include: (a) assignment to the intervention and control groups was based on the community health service teams (6 assigned to the intervention group and 5 to the control group) and this assignment was not done randomly, so strictly speaking the analysis should be based on comparing the mean results in these 11 'clusters', not on the results of all individuals who are in the intervention and control communities; (b) all the evaluations of outcome were based on self-completion forms; (c) there was no clinical assessment of participants to determine the proportion who meet diagnostic criteria for depression or anxiety disorders; (d) all the evaluations were non-blinded; and (e) we did not have data on blood pressure and fasting blood glucose before and after the intervention, so it was not possible to assess the effect of the program on the clinical status of the participants.

### 4.3 Significance

We find that clinically significant depressive and anxiety symptoms are relatively common in community residents in Shanghai being treated at local CHCs for diabetes or hypertension. Given the negative effect of these psychological problems on the quality of life and prognosis of individuals with these common chronic physical disorders,<sup>[5,6]</sup> developing effective strategies to reduce the prevalence of depressive and anxiety symptoms in these individuals is an important public

health objective. But the severe lack of mental health manpower and the stigma associated with receiving mental health treatment in low- and middle-income countries (including Shanghai), makes the individual-based psychiatric and psychotherapeutic approaches employed in high-income countries impractical. As a first step to address this problem, we implemented a 6-month multi-component community-based intervention in 62 neighborhoods in Shanghai that had a total of 10,164 individuals registered with hypertension and/or diabetes at local community health centers. There were several methodological challenges in the implementation of such a huge project – selection bias in the evaluation of the outcome, poor fidelity in the implementation of the intervention, and lack of objective measures to assess changes in the clinical status of participants – but the outcome of the study suggests that the intervention can result in improvement of both depressive and anxiety symptoms in individuals with diabetes or hypertension. Further, more rigorously implemented studies will be needed to confirm these results, but our results suggest that large-scale community-based efforts in settings where mental health resources are very limited can have beneficial results.

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### Conflict of interest statement

The authors declare no conflict of interest.

### Informed consent

Every individual who participated in this study signed a consent form or provided oral consent at the beginning of the study.

### Ethics approval

The ethics committee of the Shanghai Mental Health Center approved the study (number: 2013-36).

### Authors' contributions

YH was the principal investigator in charge of the overall design and analysis of the study, and in the review and revision of the initial manuscript; Q Zeng prepared

the initial draft of the manuscript and participated in the design, implementation, and analysis of the study; ZS participated in the design of the study and was in charge of the implementation of the intervention; WL, HT, DM, PL, and XZ were in charge of quality control for the project; XL and XQ conducted related literature searches, helped clean the data, and participated in the quality control of the interventions; Q Zhou was in charge of the data analysis.

## 综合心理干预对社区慢性病患者的效果评价：一项源于社区的整群、随机、对照试验

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**背景:** 抑郁与焦虑经常出现在慢性躯体疾病患者中, 通常这会加深这些躯体疾病所造成的损失, 但是在中低收入国家中这一问题却很少受到关注。

**目标:** 评估非专业临床人员和志愿者进行以社区为基础的心理干预对缓解慢性躯体疾病患者抑郁和焦虑症状的疗效。

**方法:** 将共计 10,164 名接受糖尿病或高血压治疗的上海社区居民任意分配到常规治疗组 (n=2042) 或干预组 (n=8122), 对干预组的干预包括社区范围的心理健康教育、同伴支持小组和个人咨询。采用自评患者健康问卷 (Patient Health Questionnaire, PHQ-9)、广泛性焦虑量表 (Generalized Anxiety Disorder scale, GAD-7) 和 12 项健康状况调查问卷 (12-item Short-Form Health Survey, SF-12) 来评定基线和干预 6 个月后的抑郁症状、焦虑症状和生活质量。

**结果:** 8813 人完成了基线评估, 其中 16% 的人有轻度或较严重的抑郁或焦虑症状 (PHQ-9 或 GAD-7 $\geq$ 5), 并有 4% 的人伴有中度或重度抑郁或焦虑症状 (PHQ-9 或 GAD-7 $\geq$ 10)。本研究有效实施了干预内容中的健

康教育部分, 但是在符合条件成为同伴支持小组的成员中仅 31% 的对象接受了干预措施, 接受个人咨询的仅 9%。本研究脱落率较高 (51%), 并且在完成和没有完成随访评估的人群之间存在显著差异。经过这些混杂因素的调整后, 在完成两项评估的对象中, 结果表明抑郁症状 (F=9.98,  $p<0.001$ )、焦虑症状 (F=12.85,  $p<0.001$ ) 以及 SF-12 中的心理部分总分 (F=16.13,  $p<0.001$ ) 均得到显著改善。然而, 自我报告未受控制的糖尿病或高血压的率没有显著变化。

**结论:** 这些结果支持了以社区为基础的干预措施的可行性, 以降低在精神科人力资源有限的中低收入国家中慢性病患者抑郁和焦虑症状的严重程度。然而, 在确认该措施广泛大规模实施前还有大量方法学上的挑战需在将来研究中解决。

**关键词:** 抑郁; 焦虑; 社区干预; 糖尿病; 高血压; 社区医疗服务; 中国

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